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September 30, 2005

Docket No. 1976N-0052G
Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Docket Management Group:

Our firm represents D&E Pharmaceuticals, Inc., a small business involved in the distribution and retailing of cold remedies, broncodialtors and other products made with ephedrine and pseudoephedrine.

The proposed rule, which would have a substantial and devastating impact on D&E and other companies that manufacture, distribute and retail cold remedies, broncodialtors and other products made with ephedrine and pseudoephedrine, requires formal comments to be submitted by November 10, 2005. This date will present a substantial hardship for D&E and other companies because D&E is a small business with limited resources and even more limited time to respond. Many of the principals of these companies have been traveling, dealing with international business emergencies and coping with legislative initiatives and legal issues caused by the Drug Enforcement Administration. All of these issues are having a substantial impact on our businesses.

Given the fact the Food and Drug Administration has been developing data in support of this proposed rule over the past 10 years, D&E believes it will be placed at a substantial economic and procedural disadvantage without additional time to formulate its comments.

Therefore, D&E hereby requests an extension of at least an additional 90 days - until February 9, 2006 - to submit its comments to the proposed rule contained in Docket No. 1976N-0052G.

Please respond to this letter as soon as possible to enable our clients to prepare an appropriate response.

Sincerely,

Kevin Weinman

KW:dm
cc: D&E Pharmaceuticals, Inc.

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